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10/585,754	07/12/2006	Marc Karel Jozef Francois	PRD2166USPCT	1592
27777	7590	11/23/2009	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			MILLIGAN, ADAM C	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## **DETAILED ACTION**

Applicants' arguments, filed 6/30/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 103***

**Claims 1-12** stand rejected under 35 U.S.C. 103(a) as being unpatentable over Heeres (WO 96/13499- See IDS dated 7/12/2006) in view of Chen (2002/0147201) and Basit et al. (The Effect of Polyethylene Glycol 400 on Gastrointestinal Transit: Implications for the Formation of Poorly Water Soluble Drugs, Pharmaceutical Research, Volume 18, No. 8, 2001).

Applicants argue that the prior art does not read on the instant claims because the prior art teaches an aqueous solution, whereas the instant claims are drawn to an oral solution. Applicants then argue that Chen does not teach that polyethylene glycol (PEG) should be incorporated into the solution for the purpose of increasing solubility. Applicants then argue that the mitratapide solutions of the present invention are not aqueous solutions, but instead use an organic solvent. Applicants state that claim 1 has been amended to include solvents of claim 2 in order to clarify this point. Finally, Applicant argue that the composition rendered obvious by the prior art would result in an

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aqueous solution of mitratapide complexed with glycyrrhizin, and therefore the prior art does not render the instant invention obvious.

Examiner disagrees. First, in response to applicant's assertion that the composition made obvious is not an oral solution, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Here, there are multiple oral formulations disclosed which may include the various active ingredients (See pp. 26-27, examples 8-10). Note, even parenteral compositions maybe administered orally where the solution is aqueous and aqueous solutions are generally accepted as orally acceptable.

Second, the teachings of Chen was not relied upon for the teaching directed to the addition of PEG-400 to the composition taught by Heeres. Basit was relied upon for the teaching that the addition of PEG-400 would enhance the solubility and bioavailability of poorly water-soluble drugs, as discussed in the Office Action dated 03/30/09. Thus, it would have been obvious to one of ordinary skill in the art to incorporate PEG-400 into the mitratapide composition taught by Heeres, because Heeres teaches that other ingredients may be included to aide in solubility and Basit teaches that the addition of PEG-400 will enhance the solubility and bioavailability of poorly water-soluble drugs (i.e. mitratapide). Chen then teaches the importance of having a preferable taste and the addition of antioxidants used to stabilize compositions.

Third, while the amendment is acknowledged, it does not overcome the rejection. Though the term "solvent" is now limited to the Markush grouping, the entire solution is modified by the transition "comprising" allows additional solvents in addition to those of the Markush grouping. Therefore, the inclusion of any solvent system with includes a solvent from the Markush grouping meets the recited limitation, even if additional solvents are present. Here, it has been demonstrated above that it would have been obvious to the skilled artisan to add PEG-400, one of the solvents instantly claimed, to the mitratapide composition taught by Heeres in order to increase the mitratapide solubility and bioavailability, as taught by Basit, which may include additional solvents.

Finally, with regards to the combination of teachings resulting in a drug complex, the skilled artisan would not rely upon only WO-96/13499 and US2002/0147201 before moving on to the additional art cited. Note, the above stated rejection is not the claims are obvious in light of the first two pieces of prior art, the combination further in view of the tertiary art, but instead the instant claims are obvious over the primary art in view of the two secondary pieces of prior art. As such, Examiner asserts the skilled artisan would look to WO-96/13499, and then look to other art for a means of overcoming the solubility problem, such as disclosed in Basit et al, where solubility is a problem with the drug, as taught by US2002/0147201. Thus, the skilled artisan need not be use a drug complex to overcome the solubility issue, but would find it obvious to use the solubility enhancing agents of Basit et al, and relying on US2002/0147201 for additional agents which may stabilize the composition and the teaching of the solubility problem of the active agent.

***Conclusion***

No claims allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM MILLIGAN whose telephone number is (571)270-7674. The examiner can normally be reached on M-F 9:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fred Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612

/A. M./  
Examiner, Art Unit 1612